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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,134	01/29/2001	David A. Lightfoot	1268/4/2	9557
25297	7590	02/13/2004	EXAMINER	
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/772,134

**Applicant(s)**

LIGHTFOOT ET AL.

**Examiner**

David H Kruse

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11,13-15 and 17-80 is/are pending in the application.  
4a) Of the above claim(s) 1-10 and 27-70 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 11,13-15,17-26 and 71-80 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11-03.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This Office action is in response to Applicant's reply received in the Office on 7 November 2003.
2. The IDS filed 7 November 2003 has been considered, a signed copy is attached hereto. Reference 3 has been lined through because this reference had been previously cited in the PTO-892 form attached to the previous Office action.
3. Those rejections/objections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
4. This application contains claims 1-10 and 27-70 drawn to an invention nonelected without traverse in the response filed 16 January 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

6. The abstract of the disclosure remains objected for the reasons given in the previous Office action. Applicant's traversal of the objection in the Response on pages 18-19 is noted. The Examiner reserves the right to amend the Abstract or require Applicant to amend the Abstract as outlined in the MPEP § 1302.01 at such time that the claims are found to be allowable.
7. The disclosure remains objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant's amendment to the

specification is not deemed adequate, it is recommended that <http://www>. be deleted (page 2 of the Replay). See MPEP § 608.01.

***Claim Rejections - 35 USC § 101***

8. Claims 11, 13-15, 17-26 and 71-80 remain rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. This rejection is repeated for the reason of record as set forth in the last Office action mailed 7 May 2003. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

Applicant argues that claims 14-15[sic], 73 and 74 have been amended and the nucleotide and amino acid sequences are specifically recited in the amended claims (page 22, 2<sup>nd</sup> paragraph of the Remarks). This argument is not found to be persuasive because as previously stated, the nucleic acid sequence of SEQ ID NO: 13 and the amino acid sequence of SEQ ID NO: 14 are not completely defined, nor do they appear to teach a complete gene product. In addition, claims 11, 13, 17-26, 71, 72 and 75-80 are directed to products and methods using nucleic acids not taught by Applicant.

Applicant argues that the art teaches that the Rhg1 locus for soybean cyst nematode is co-dominant and thus a nucleic acid encoding the Rhg1 gene product would have a utility in view of Meksem *et al* (2001) (Page 22, 3<sup>rd</sup> paragraph of the Remarks). The Examiner concedes this argument in view of the teachings of Meksem (2001).

***Claim Rejections - 35 USC § 112***

9. Claims 11, 13-15, 17-26 and 71-80 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and use the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 7 May 2003. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

Applicant's argument concerning the issue of dominance of the Rhg1 locus in soybean as been addressed above (page 24, 1<sup>st</sup> paragraph of the remarks).

Applicant argues that the limitation "encoding a biologically active SCN/SDS resistance polypeptide" has been misinterpreted, and that according to the specification as filed, "the term 'SCN/SDS resistance or 'SCN/SDS resistance trait' as used herein refers to a cellular or organismal capacity for resistance to nematode or fungal infection, or both" and that it is not necessary that a nucleic acid molecule of the presently disclosed subject matter to confer both SCN and SDS resistance (page 24, 2<sup>nd</sup> paragraph of the Remarks). This argument is not found to be persuasive because cellular or organismal capacity for resistance does not teach one of skill in the art how to make and use the invention within the meaning of the claims, see for example claim 11. In addition, claim 11 encompasses a dual function resistance polypeptide, an example of which Applicant does not teach.

Applicants argue that the guidance for identifying and isolating a nucleic acid encoding an SCN/SDS resistance polypeptide is sufficient, and that Examples 3 and 4 clearly demonstrate to the skilled artisan the identification and isolation of a nucleic acid encoding an SCN/SDS resistance polypeptide (page 24, 3<sup>rd</sup> paragraph of the Remarks). This argument is not found to be persuasive because it is clear from the nucleic acid sequence of SEQ ID NO: 13 that Applicant does not teach a complete coding sequence for a polypeptide and the specification invites experimentation by one of skill in the art to isolate the complete coding sequence and confirm the function. See page 40, lines 17-21 of the specification, which states, "The rhg1 sequences disclosed herein can also be used to isolate rhg1 cDNAs according to methods well-known in the art. A representative rhg1 partial cDNA is set forth as SEQ ID NO: 122".

Applicant arguments that the teachings of Duggleby *et al* is not applicable to the instant claims is not found to be persuasive because the Examiner has cited Duggleby *et al* to teach that one of skill in the art cannot infer function of a nucleotide coding sequence or encoded polypeptide simply based on similarity to other known sequence (page 25, 1<sup>st</sup> paragraph of the Remarks). In the instant case, Applicant does not teach the specific function of either the Rhg1 or Rhg4 gene in a soybean plant, only the phenotype conferred thereby, cyst nematode resistance.

Applicant argues that the Examiners arguments directed to the function of the claimed construct used in the claimed method would not have a functional use in any other plant other than soybean is unsupported by any scientific reasoning (page 25, 2<sup>nd</sup> paragraph of the Remarks). This argument is not found to be persuasive because

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Applicant does not teach that soybean cyst nematodes infest a broad range of plants and that the resistance mechanism in soybean could be transferred to plants other than soybean.

Applicant's arguments as directed to SCN resistance associated with Rhg1 as a resistive gene have been addressed above (page 25, 3<sup>rd</sup> paragraph to page 26 1<sup>st</sup> paragraph of the Remarks).

10. Claims 11, 13-15, 17-26 and 71-80 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 7 May 2003. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

Applicant argues that the teachings of *Eli Lilly* do not apply and that claim 11 has been amended to recite an isolated and purified soybean nucleic acid molecule encoding a biologically active SCN/SDS resistance polypeptide. In addition, Applicant argues that SEQ ID NO: 13 represents a sequence encoding a biologically active SCN/SDS resistance polypeptide (page 27, 2<sup>nd</sup> paragraph of the Remarks). This argument is not found to be persuasive because the invention at claims 11, 13, 17-26, 71, 72 and 75-80 are directed to nucleic acid molecules and methods of using them described solely by function. Claims 14, 15, 73 and 74 are not adequately describe

because the nucleic acid sequence of SEQ ID NO; 13 comprises undefined nucleic acids and it is unclear from the written description that it describes a complete coding sequence, and the amino acid sequence of SEQ ID NO: 14 comprises undefined amino acids.

Applicant argues that the instant specification contains not only a method of making plus a description of function, but also explicit disclosure of nucleic acid sequence data and other data for nucleic acids encoding polypeptides with those functions (paragraph spanning pages 27-28 of the Remarks). This argument is not found to be persuasive because nowhere in the specification does Applicant establish the function of the described nucleic acids and encoded polypeptides. As stated above, it remains unclear that Applicant has isolated a nucleic acid molecule encoding the Rhg1 gene product.

Applicant argues, the biomolecule is not described solely by a functional characteristic. Sequence data for the genes themselves is also included. Applicants argue that between SEQ ID NO: 13, which corresponds to Rhg1 and any one of SEQ ID NOs: 16-19, which correspond to Rhg4, there is over 98% sequence identity. Applicants argue that one of ordinary skill in the art would recognize that there is a disclosed correlation between the function described and the structure of the sequence (page 28, 2<sup>nd</sup> paragraph of the Remarks). These argument are not found to be persuasive because SEQ ID NO: 13 and SEQ ID NOs: 16-19 do not completely describe Rhg1 or Rhg4. The specification states that these are partial sequences (see page 40, lines 18-19 and the Sequence Listing in the specification).



Applicants argue that given the teachings of the instant specification in conjunction with the soybean Rhg4 gene sequences explicitly disclosed in SEQ ID NOs: 16-19, it would have been apparent to the ordinary artisan that applicants were in possession of the claimed subject matter (page 28, 3<sup>rd</sup> paragraph of the Remarks). This Examiner has addressed this argument above.

Applicants argues that as disclosed in the specification of the instant application, the genomic clone described in the specification containing the soybean Rhg4 gene is available from the Forrest BAC library described in Meksem *et al.* (2000, 101 Theor Appl Genet 747-755) through Southern Illinois University- Carbondale (Carbondale, Illinois), Texas A&M University BAC center (College Station, Texas), and Research Genetics (Huntsville, Alabama) (page 28, 4<sup>th</sup> paragraph of the Remarks). This argument is not found to be persuasive because it is clear from the last sentence, left column on page 716 of Meksem (2000) that the Rhg1 and Rhg4 loci had not been yet sequenced, only that a location has been identified on linkage groups G and A2, respectively, where the loci are located.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



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David H. Kruse, Ph.D.  
4 February 2004